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THALER, M EXAMINER

33M1/0826

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ART UNIT	PAPER NUMBER
3309	7

DATE MAILED: 08/26/94

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☑ This application has been examined ☑ Responsive to communication filed on 6-2-94 ☐ This action is made final

A shortened statutory period for response to this action is set to expire 3 month(s), _____ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☐ Notice of References Cited by Examiner, PTO-892.
2. ☑ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☑ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☑ Claims 18-29 are pending in the application.
   Of the above, claims 18-22 are withdrawn from consideration.
2. ☑ Claims 1-17 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☑ Claims 18, 23-29 are rejected.
5. ☐ Claims _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____ ; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

U.S. Patent No. 1,596,284, which was cited in the information disclosure statement filed August 10, 1994, is not relevant to the invention. If a different patent no. was intended to be cited, this patent no. is requested.

Claims 19-22 are withdrawn from further consideration by the examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected species. Election was made **without** traverse in Paper No. 5.

Claims 26-27 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 26, it is unclear if the guidewire is part of the claimed combination. In paragraph e), the phrase "a guidewire slidably disposed within the guidewire receiving inner lumen" suggests that it is. Yet it is not clearly positively recited. In claim 27, line 2, "has with the" is not understood.

Claims 18, 23 and 26-29 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 5,061,273. Although the conflicting claims are not identical, they are not patentably distinct from each other because the inclusion of a guidewire (defined in the application claims) would certainly have been obvious in view of the reference to a guidewire in the patent claims.

Claims 24-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 5,040,548. Although the conflicting claims are not identical, they are not patentably distinct from each other because it certainly would have been obvious to hold the portion of the guidewire which extends out of the proximal guidewire port (as defined in the application claims).

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. *In re Vogel*, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d).

Claim 18 is rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Enzmann et al. Enzmann et al. show catheter 50, distal guidewire port 52, proximal guidewire port 61, means 53 to perform an intravascular procedure which is spaced closer to the distal guidewire port than the proximal guidewire port and guidewire 64. The Enzmann et al. catheter is capable of being advanced within a coronary artery. Alternatively, it is obvious that the Enzmann et al. catheter is capable of being advanced within a coronary artery.

Claims 23 and 26-27 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103 as obvious over Gants. Gants shows catheter shaft 32, 30, balloon 28

with the distal end of the balloon being spaced closer to the distal guidewire port (near 36) than the proximal end of the balloon is spaced from the proximal guidewire port (at the top of member 30 as seen in figs. 1, 2 and 4) and guidewire 12. The Gants catheter is inherently capable of being used in a patient's artery to perform an angioplasty procedure. Alternatively, it is obvious that the Gants catheter is inherently capable of being used in a patient's artery to perform an angioplasty procedure. As to claim 26, the Gants catheter is inherently capable of fitting into a coronary artery of a large person or animal.

Claim 24 is rejected under 35 U.S.C. § 103 as being unpatentable over Nordenstrom (1965). It is obvious that the surgeon would hold the proximal portion of the Nordenstrom guidewire until the means to perform an intravascular procedure is positioned within a desired location within the patient's artery.

Claims 25 and 28 are rejected under 35 U.S.C. § 103 as being unpatentable over Weikl et al. Note fig. 3 of Weikl et al. It is obvious that the Weikl et al. procedure may broadly be considered "angioplasty". In any event, assuming arguendo that it is not so considered, it would have been obvious to use balloon 5 of Weikl et al. to dilate any arterial occlusion which remains after the occlusion dissolving procedure has been completed, particularly since such balloons have been well known to perform this dilatation procedure to expand the occlusion. As to claim 28, it is obvious

that one of the lumens 12, 13 would be located in the Weikl et al. shaft 16 in the fig. 3 embodiment.

Claims 28-29 are rejected under 35 U.S.C. § 103 as being unpatentable over Gants. Including an additional lumen in the Gants shaft 32, 30 in order to provide additional fluid infusion would have been obvious.

Claims 24-26 and 28 are rejected under 35 U.S.C. § 103 as being unpatentable over Bonzel "A New PTCA System With Improved Steerability...". As to claims 24-25, the procedure claimed would have been obvious in view of the Bonzel brief disclosure. As to claim 26, it is obvious that the Bonzel catheter has an inflation lumen in order to inflate the balloon. As to claim 28, including an additional lumen in the Bonzel shaft in order to provide fluid infusion would have been obvious.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Thaler whose telephone number is (703) 308-2981.

MICHAEL THALER
PRIMARY EXAMINER
ART UNIT 3309

mht
August 24, 1994